ALS
ANGELANTONI
LIFESCIENCE

Catalogue of special products

STERIL

Angelantoni Industrie began operating in 1932 in the refrigeration field, and over the years it has become increasingly specialized in the biomedical sector with the technological and scientific applications of refrigeration, but also in the broader field of laboratory equipment, such as laminar flow hoods and controlled contamination environments.

Today Angelantoni Industrie S.p.A. (Holding), comprises three separate subholdings:

Angelantoni Life Science S.r.l. (ALS) with the main brands AHSI – AS – STERIL – AG – ACOTEC (biomedical equipment, controlled contamination environment equipment, laminar flow hoods and clean rooms, instruments and furnishings for research laboratories, health facilities and the pharmaceutical industry);

Angelantoni Test Technologies S.r.l. (ATT) with the main brands ACS – TIRA – BIA – AMEC – AKI (environmental test chambers and space simulators, test benches for the automotive industry, electrodynamic shakers, balancing systems);

Angelantoni CleanTech S.r.l. (ACT) with the main brands SOLARLIGHT – 3RAYS – KENOSISTEC – ELIANTO – ENTERPRISE (photovoltaic plants for asbestos replacement, photovoltaic greenhouses, concentration photovoltaic systems, solar thermal power plants with Fresnel reflectors, equipment for thin film technology coating, biogas power plants).

Associated with ACT, but with a separate structure, ARCHIMEDE SOLAR ENERGY designs and produces molten salt solar receiver tubes, superheated oil and steam (DSG) for solar thermal power plants with parabolic or flat (Fresnel) reflectors.

Today the ANGELANTONI group includes 8 production units located in Italy, Germany, France, India and China, with a total of over 850 employees and turnover of 145 million Euro.

STERIL can boast of a long series of national and international successes thanks to its continual innovation. This division of ALS designs and manufactures horizontal and vertical laminar flow cabinets, biohazard and cytostatic safety cabinets, laminar flow pass boxes with UV light, sterilising pass boxes using Hydrogen Peroxide, cabinets for weighing, sampling and dispensing, and isolators, in compliance with the most recent international standards (cGMP-current Good Manufacturing Practice).

The STERIL engineering team faces challenges from the market on a daily basis by offering a wide range of innovative, flexible and versatile products, which have been carefully researched to provide top quality and reliability.

The excellent skills of the technical staff ensure a turn-key product and provide exclusive, stable customer relationships, which over the years have been perfected by after-sales customer service and the supply of spare parts.

As a result, Steril is able to meet the needs of its numerous, major clients, including hospitals, universities, industries in the pharmaceutical, biotechnological, diagnostic, veterinary and food & beverage sectors.

Steril provides numerous solutions to problems concerning high containment by combining flexibility and a good quality/price ratio. Steril's approach is based on excellent project design and the implementation of solutions to fulfil the customers' requirements.

Steril can offer a wide range of special equipment to protect both the operator and the product in various sectors, including:

- Pass box;
- Powder weighing and dispensing cabinet;
- Safety cabinet for cytostatic drugs;
- "Down cross" Cabinet for sampling and dispensing;
- Isolators;
- Containment systems (RABS);
- Vertical laminar flow modular systems.

ALS-Steril guarantees attentive, after-sales customer service as regards both product installation and maintenance of its product safety conditions over time. Its qualified staff undergo regular, professional, refresher courses to ensure customers are given a top quality, crucial and reliable service.

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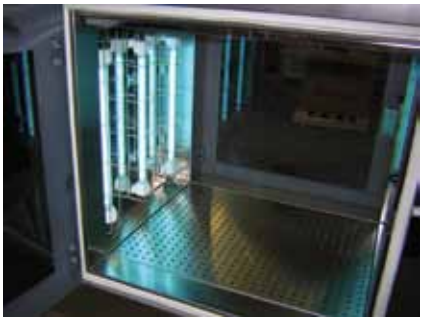
1. Pass box

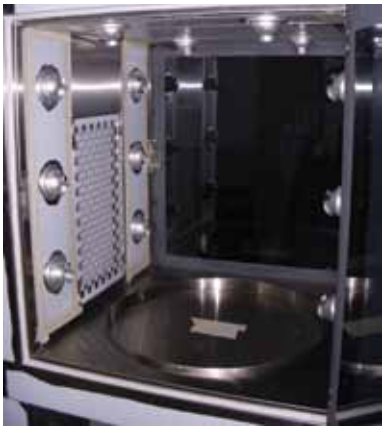


Internal chamber of the pass box with UV lamps switched on

This enables products to be transferred between two, differently classified rooms so that it actively separates the two environments. The product is inserted from the non-sterile, contaminated side and is cleaned by a jet of filtered air. The doors are controlled by a system that avoids both doors from opening simultaneously, thus preventing the cleaner environment from being contaminated.

Internal chamber of the pass box with hydrogen peroxide nebuliser

The principle behind this operation is based on the vertical laminar flow which passes through the pass box from top to bottom. It maintains a cleaning level of ISO 5 inside the Box, which is, therefore, higher than the entry environment of the product. The filter unit consists of an electric blower and a HEPA filter which guarantee constant clean conditions. This is done by constantly recirculating the internal air and part of the intake air is filtered through a special opening at the top of the cabinet.



Internal chamber of the pass box with nozzles on three sides and a revolving plate

This enables the internal chamber to be maintained under a slightly positive pressure to create a pressure differential between the two adjacent rooms. Door locking is electrically controlled by a computer for the entire length of the sterilisation cycle. In the event of an emergency, such as a blackout during the decontamination cycle, the door on the contaminated side automatically unlocks, so the product inside the box can be removed. On request, the ultraviolet rays produced by the UV lamps on the side walls of the pass box or the hydrogen peroxide (H_2O_2) nebuliser can be used to sterilise micro-organisms at the same time as laminar flow decontamination is taking place.

2. Air shower

This enables staff entering a contamination controlled area (clean room) or leaving areas where dust polluted or contaminated products are handled to be decontaminated. The air shower is usually installed at the entrance to the clean room. Inside the shower, the operator receives a blast of high speed (approximately 25 m/sec), Class ISO5 air which removes inert or active particles from his clothing. The contaminated air is vented through the grids and passed over the pre-filtration bench in the lateral cavity of the structure.

Air shower.

3. Powder weighing and dispensing cabinet

The CDP cabinets are suitable for handling pharmacologically and chemically active substances while the operator is outside the air flow (OEL containment grading >100 µg/m³).
The system uses a vertical, ISO5 Class, laminar air flow with a recovery section equipped with an absolute HEPA filter on the recovery and recirculation channel. The cabinet provides partial recirculation of air treated with a portion of the air discharged into the surrounding environment after opportune, absolute filtration.

Powder weighing and dispensing cabinet inside a classified environment.

The operator and the product are protected from cross-contamination by containing powder handling within the area, thanks to a slightly lower pressure inside the cabinet compared to the outside environment and to an airflow barrier installed at the front opening to allow work operations.
A portion of the air filtered by a HEPA H14 filter is sent to the area to guarantee a perfectly clean work area.

4. Safety cabinet for cytostatic drugs

Cytobox

Cytobox

Steril designs, manufactures and tests customised Cytoboxes for pharmaceutical companies to dispense/sample cytostatic drugs in a Class A work area in compliance with "GMP" and "EU" standards (please refer also to our catalogue of standard products).

Glove box

The microbiological Glove Box cabinets are designed and constructed with a physical barrier to keep the operator separate from the product being handled.

5. "Down cross" Cabinet for sampling and dispensing

Down Cross Cabinet

The Down-Cross system was designed to enable the operator to handle and dispense non-sterile products with powders and/or volatile compounds so that pharmaceutical product batches can be weighed and prepared entirely under LAF (Laminar Air Flow). The features of the cabinet can guarantee protection of the operator, product and surrounding environment. The operator and the product are protected from cross-contamination by containing powder handling within the area, thanks to a slightly lower pressure inside the cabinet compared to the outside environment and to an airflow barrier installed at the front opening to allow work operations.

The principle behind the DOWN CROSS equipment is based on the work area being continually washed with filtered, ISO5 class, laminar air flowing from top to bottom in compliance with ISO EN 14644-1.

The cabinet provides partial recirculation of air treated with a portion of the air discharged into the surrounding environment after opportune, absolute filtration. The "Down-Cross" system uses a vertical, ISO5 class, laminar air flow on 0.5 and 5 micron particles under "at rest" conditions, in compliance with the ISO 14644-1 standard. It includes a recovery section complete with double stage pre-filtration on the vertical, rear wall.

In addition, the cabinet is equipped with a temperature control system. 90% of the recirculating air is vented into the lower area from the grids through a first stage of filtration consisting of G3 filter cells (EN779). The air then passes to a second stage of filtration consisting of dihedral, F9-type pre-filters.

Internal detail of the cabinet with UV lamps switched on.

A portion of the air is vented through the HEPA H14 filters (in compliance with EN1822) in order to maintain the work area at a slightly lower pressure. This results in external air being sucked into the lower part of the perimeter screens at floor level and this prevents the powders from dispersing into the surrounding environment. The final filtration uses HEPA H14 filters in compliance with EN 1822 standards.

Detail of the control panel.

The Down-Cross cabinet can also be designed and constructed for use in ATEX classified environments in compliance with the directive 94/9/EC concerning equipment and protection systems intended for use in potentially explosive atmospheres.

6. Isolators

The isolator is a system with a product handling area which is completely isolated from the surrounding environment. It usually consists of a work chamber and a pass box to load the materials inside.

6.1 Isolator under negative pressure

The system is suitable for handling pharmacologically and chemically highly active substances. The work chamber has a pressure control system, which acts on the speed of the exhaust ventilator. Pressure values can be regulated from between - 50 Pa and - 100 Pa. The gloves for product handling are installed on the front screen on double grooved flanges holding O-Rings, so they can be replaced safely. The products to be handled enter the isolator work chamber via a pass box equipped with interlocked doors. Moreover, the equipment has a "Linear Bag" or RTP system to release any depleted products, as well as a cleaning and decontamination system complete with a system to capture waste discharge.

Isolator for sampling & dispensing

The isolator is made of AISI 316 L with continuous welding and wide bend radius; a material discharge system using a "barrier bag" or RTP system.; an exhaust, "PUSH-PUSH", air filtration system with a double HEPA filter; an air/nitrogen supply system with the installation of one or two cartridge filters with a retention grade of 0.2 µm, or HEPA filters; an indicator for load loss of discharge and supply filters; a front facing, fixed or movable screen, made of multi-layered safety glass; set up for WIP (Washing in Place); "PLC"-managed control system; cabinet low pressure control via self-adjusting fan; an air exhaust system capable of increasing capacity to guarantee a speed of 0.7 m/s in the event of a glove tearing.

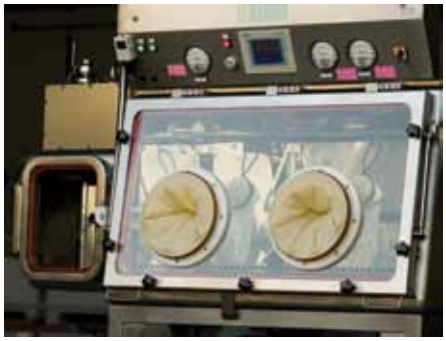
Isolator for sterility test.

In its configuration for compounding/dispensing the isolator is normally used to fill the reaction (compounding) vessels directly or to fill the dispensing "Bins". In both cases, the highly active substance is introduced into the handling chamber via a pre-chamber. The product is unloaded into the reactor or "Bin" in the handling chamber. The reactor in the "compounding" isolator is placed in a charge cell so the precise quantity of active substance required can be dispensed. In this case, the isolator work surface will carry a special seal so that it does not interfere with the weighing process, but continues to guarantee complete isolation of the active substance. In the "dispensing" isolator, the work surface will be equipped with a high containment valve, so that the "Bin" below can be filled in complete safety.

The isolator can also be designed and constructed for use in ATEX classified environments, in compliance with the directive 94/9/EC concerning equipment and protection systems intended for use in potentially explosive atmospheres.

6.2 Isolator under positive pressure

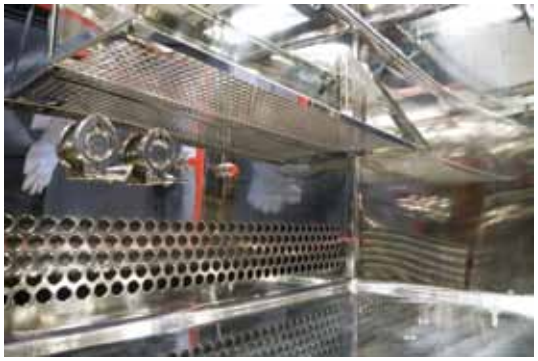
Isolators under positive pressure are designed for situations which require a high level of product protection from microbiological and particle contamination. A front screen physically separates the internal and external environments, so that handling operations cannot contaminate the product. The sleeves of the gloves used for handling are made of latex and the remaining part is made of Hypalon rubber. The isolators are mainly used for sterility tests which require an internal class A environment (GMP classification Annex 1). The quantity of exhaust air is compensated by an equal quantity being sucked in from the surrounding environment by a special double inlet fan, using an innovative motor with an integrated frequency converter. This air is then filtered by an absolute, H14 efficient filter.



Isolator, general view

Internal detail of an isolator

The air sucked into the work chamber is filtered by an H14 efficient HEPA filter. The amount of exhaust air remains constant at approximately 15% of the total capacity. The intake air capacity is managed by a regulating loop, which guarantees pressure inside the work chamber is maintained above that of the surrounding environment. The exhaust air is filtered further by a HEPA H14 filter to guarantee the total absence of any particles exiting from the chamber to the outside. Furthermore, it guarantees that the internal environment of the cabinet remains clean, even when the cabinet is not running. The product is, therefore, protected by a physical barrier from the outside, by an overpressure in the chamber and by a flow with a speed of 0.45 m/s ± 20% measured 10 cm below the HEPA delivery filter. This gives an improved classification of the area with an ISO5 class in compliance with the EN 14644-1.



Internal details of isolators.

The isolator can be fitted with a liquid discharge and a shelf inside the main chamber to be used in support of any equipment required for processing. The isolator can also be fitted with a hydrogen peroxide sterilisation system.

The isolator is equipped with a dual function pass box:

- To allow incoming material to be sterilised using the appropriate hydrogen peroxide cycle. For this reason, the outer hermetic shell will be guaranteed to be class 3, in compliance with ISO 10648-2. Furthermore, the door between the pass box and the isolator chamber will not be able to be opened during the sterilisation cycle to guarantee the operator's safety as requested by the machine directive.

- To extend the work area in which to place the material to be discharged from the isolator. As regards the latter, the pass box is equipped with a discharge HEPA filter, so that during operations with the door to the chamber open, it receives a jet of sterile air, which can avoid any particles contaminating the main chamber.

7. RABS containment systems

The RABS (restricted-access barrier systems) systems provide a very high aseptic quality level. RABS systems guarantee protection by providing an aerodynamic barrier to a critical processing area. When RABS are installed in ISO7 environments, they already have a clean-room air class and are, therefore, able to provide ISO5 quality in a critical area.
The purpose of the system is to contain dispersion of powdered products during packaging (product protection) and to reduce the risk of exposure for the member of staff handling the product (operator protection).
The RABS are not hermetically sealed, but use a dynamic barrier created by the air flow into the chamber. Under work conditions the system is designed to use a dedicated, aeraulic circuit to maintain a slightly negative pressure (low pressure) compared to the outside environment.

ALS has identified and assessed, according to the requirements for production and for the safe use of the system, the following essential factors for the design:

- operator protection and safety;
- containment of the area in which the product is exposed;
- ergonomics;
- protection of the external environment;
- rigid walls, which physically separate the operators and production.

ALS can provide different types of RABS including:

- an open RABS: once the air has passed over the protected area, it is sent to the clean room without any further discharge filtration;

- a closed RABS: after the air has passed over the critical area, it is filtered before being sent into the clean room or it is recirculated though the RABS filters.

RABS

The strength of a group which draws from past knowledge to better interpret and anticipate the future.

Situated in Massa Martana in the province of Perugia, the head office of Angelantoni Industrie stretches across an area of over 80,000 square metres, over 16,000 of which are under cover. Massa Martana lies in Umbria, a region rich in art, history and tradition. A rather appropriate location: Angelantoni Industrie S.p.A. draws from past knowledge to better interpret and anticipate the future. All this, together with its dedication and constantly developing know-how has led Angelantoni Industrie S.p.A. to become the most comprehensive and most widely diversified group in advanced refrigeration technology and devices for industrial and research testing and trials.

Our skills and principle services to satisfy our customers include:

- Training: at our plants and at the customer's headquarters.
- Testing and quality assurance checks.
- Installation and set-up.
- Customer service.
- Calibration using SIT (Italian calibration service) certified tools.
- "All-risk" service contracts.
- Special applications /Turn-key projects.

Quality, Safety & Environment

Sustainable development for a company wishing to grow and improve does not merely presuppose attention to technology and innovation, but also to the environment, safety and interpersonal relationships. If ISO 9001 certification guarantees respect for standards, efficient processes and Customer satisfaction, Angelantoni Industrie has also introduced a System of Integrated Management to prove it is possible to work according to Quality Assurance and to manufacture products in compliance with regulations which respect the environment and the safety of both the products and the people for whom they were intended, to provide not only continual Prevention and Improvement, but also Customer satisfaction.

Angelantoni Industrie has achieved the following certifications:

- NATO AQAP 104 in 1991.
- ISO 9001 in 1995.
- ISO 14001 in 2001.
- EMAS (registration number IT-001058) in 2008.
- Product certifications for HEMONINE 2, HEMOSAFE, IRIDIUM from 2008.

Furthermore, we guarantee:

- The standards SA8000, OHSAS 18001, SGLS since 2001.
- Compliance with the Directive 2002/95/EC (RoHS directive).
- RAEE (waste electric and electronic equipment) registration (registration number IT 08020000003520).

Moreover, in 2009 it obtained the ISO 13485:2003 certification and the CE 93/42 marking for medical devices with their registration at the Ministry of Health. These certifications require the company to maintain the configuration status of its medical Devices, to update its staff, to constantly check the performance of the Medical devices, to rigorously analyse any complaints and non-conformities, and to provide a more collaborative relationship with its customers regarding any critical points.

ALS ANGELANTONI LIFESCIENCE

Biomedical equipment for storage at low temperatures (+4°C/-150°C) and chambers for stability tests

Refrigerating systems for industrial processes

Project design and implementation of controlled contamination environments

Laminar flow equipment for laboratory:

1. Class II microbiological safety cabinets
2. Cabinet for cytostatics
3. Class 100 (ISO5) cabinets
4. Cabinet for micro-weighing
5. Stabulary cabinets
6. Cytobox
7. Laminar flow modules

Industrial Equipment:

1. **Pass box**
2. **Air shower**
3. **Weighing and dispensing Cabinet**
4. **Safety Cabinet for cytostatic drugs**
5. **"Down Cross" Cabinet for sampling and dispensing**
6. **Isolators**
7. **RABS Containment System**



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Angelantoni Life Science S.r.l.
Località Cimacolle, 464 - 06056 Massa Martana (PG) Italy
ph. (+39) 075.89551 (a.r.) - fax (+39) 075.8955312
E-mail: biomedical@angelantoni.it
www.angelantonilifescience.it

STERIL branch offices,
Viale Monza, 291 - 20126 Milano, Italy
ph. (+39) 02.9397011 fax (+39) 02.93970121

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